



Parenteral Quality Control: Sterility, Pyrogen, Particulate, and Package Integrity Testing (Drugs and the Pharmaceutical Sciences)

Michael K. Akers, Dan Larrimore, Dana Guazzo

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Providing a well-written and easy-to-read review of the subject, this reference describes the most recent breakthroughs in the validation and execution of testing schemes for parenteral quality control. Emphasize testing methodologies for the evaluation of package integrity, finished product contamination, and sterility, the book is a guide to testing and assuring that products for injecting drugs are sterile, free from pyrogenicity, and free from particulate matter. The authors highlight methods that meet US and European standards, explain regulatory requirements and harmonization between various authorities, and review trends and recent developments in technology.

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